510(K) Summary

This 510(K) Summary of safety and effectiveness for the PelleFirm System is submitted in accordance with the requirements of the SMDA 1990 and FDA guidance concerning the organization and content of a 510(K) summary.

Applicant:	Ellman International
Address:	Ellman International 400 Karin Lane Hicksville, NY 11801
Contact Person:	Alison Sathe
Telephone/Email/Fax:	513-658-8960 asathe@ellman.com 516-267-6750
Preparation Date:	February 20, 2014
Device Trade Name:	PelleFirm System
Common Name:	Massager, Vacuum, Radio Frequency Induced Heat
Classification Name:	Massager, Vacuum, Radio Frequency Induced Heat, PBX, 878.4400
Legally Marketed Predicate Device(s):	truSculpt (Cutera K122389)

Device Description:
The device is a hand-held RF probe with integrated massaging head. The device is activated using a footswitch and is used with the Ellman radiofrequency generators. The radiofrequency generator operates at 4 mHz and is used in the pure sinewave ("CUT") mode to produce heating for the elevation of tissue temperature.

Intended Use:
The PelleFirm RF component is intended use is to generate deep heat within the body tissues for selected medical conditions such as the temporary relief of minor aches and pain, muscle spasms, and an increase in local circulation. The PelleFirm massage component is also intended to provide temporary reduction in the appearance of cellulite.

The PelleFirm indications for use are:

> The PelleFirm RF device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.
> The PelleFirm massage device is intended to provide a temporary reduction in the appearance of cellulite.

Technological Characteristics:
The PelleFirm System consists of the PelleFirm handpiece, RF generator, neutral plate, Gel, Footswitch, and associated cables and cords. The handpiece contains a large monopolar electrode to provide tissue heating. A massaging head surrounds the handpiece electrode and provides mechanical stimulation to the tissue to reduce the appearance of cellulite. A cable connects the handpiece to the RF generator.

Performance Data:
The system has been tested and found to be in conformity with IEC 60601-1 and IEC 60601-2-2. Clinical performance testing demonstrates the device's ability to heat tissues consistently for an extended period of time. In all testing, the device functioned as intended and tissue heating was observed as expected.

Substantial Equivalence:
The PelleFirm System is as safe and effective as the predicate device. It has the same intended uses and similar indications, technological characteristics, principles of operation as its predicate device. The technological differences between the PelleFirm and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the PelleFirm is as safe and effective as the truSculpt device. Thus, PelleFirm System is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 20, 2014

Ellman International, Inc.
Alison Sathe, Director of Regulatory and Clinical Affairs
400 Karin Lane
Hicksville, NY, 11801

Re: K132949
Trade/Device Name: Pellefirm System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: PBX
Dated: January 16, 2014
Received: January 22, 2014

Dear Ms. Alison Sathe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel

for Binita S. Ashar, MD, MBA, FACS
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132949

Device Name
PelleFirm System

Indications for Use *(Describe)*
The PelleFirm RF device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.

The PelleFirm massage device is intended to provide a temporary reduction in the appearance of cellulite.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.02.20 16:36:08 -05'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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